PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
07039-404WO1		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US03/06380	28 February 2003 (28.02.2003)	01 March 2002 (01.03.2002)
International Patent Classification (IPC) or national classification and IPC		
IPC(7): G01N 33/48, 33/53, 33/555, 33/567 and US Cl.: 435/7.24; 436/63		
Applicant		
MAYO FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of report with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
30 September 2003 (30.09.2003)	10 February 2004 (10.02.2004)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Valerie Bell-Harris for Patricia A. Duffy Telephone No. 703-308-0196

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/06380

I. Basis of the report

1. With regard to the elements of the international application:*

☒ the international application as originally filed.

☒ the description:
pages 1-38 as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the claims:
pages 39-46, as originally filed
pages NONE, as amended (together with any statement) under Article 19
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☒ the drawings:
pages 1-24, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

☐ the sequence listing part of the description:
pages NONE, as originally filed
pages NONE, filed with the demand
pages NONE, filed with the letter of _____.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/~~fig~~ NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

*** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The question whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application,

☒ claims Nos. 7-58

because:

☐ the said international application, or the said claim Nos. ____ relate to the following subject matter which does not require international preliminary examination *(specify)*:

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. ____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. ____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 7-58

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty (N)	Claims 6	YES
	Claims 1-5	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-6	NO
Industrial Applicability (IA)	Claims 1-6	YES
	Claims NONE	NO

2. CITATIONS AND EXPLANATIONS

Claims 1-5 lack novelty under PCT Article 33(2) as being anticipated by Yasuko Ikeda et al (Japanese Journal of Allergology, 48(5):546-553, 1999).

Yasuko Ikeda et al teach methods of degranulation of eosinophils by IgG antibody to fungal antigen. The assay comprises coating the wells of a microtiter plate with an extract of Candida albicans and then IgG antibody was immobilized on the wells by incubation with patient's serum. After cultivation of eosinophils on the well, degranulation of eosinophils, was assessed by quantitation of EPX in the supernatant. Yasuko Ikeda et al teach inhibition of IgG degranulation by preincubation of the eosinophils with anti-CD32 antibody or anti-CD18 antibody. As such, the method of Yasuko Ikeda et al destroys the novelty of the claimed invention.

Claim 6 lacks an inventive step under PCT Article 33(3) as being obvious over Yasuko Ikeda et al (Japanese Journal of Allergology, 48(5):546-553, 1999).
in view Ohashi et al (J. Antibiot. 50(11):972-974, 1997).

Yasuko Ikeda et al is set forth supra. Yasuko Ikeda et al differ by not measuring eosinophil degranulation by using eosinophil derived neurotoxin.

Ohashi et al teach the amount of degranulation of eosinophils can be measured by ELISA for eosinophil derived neurotoxin (see page 973, column 1, Figure 2).

It would have been prima facie obvious to one having ordinary skill in the art at the time that the invention was made to alternatively measure eosinophil degranulation in the method of Yasuko Ikeda et al using the ELISA for eosinophil derived neurotoxin because Ohashi teach that the amount of degranulation of eosinophils can be measure using eosinophil derived neurotoxin. The substitution of one eosinophil degranulation marker for another is routine in the art, where multiple markers or eosinophil degranulation exist because the markers are functionally equivalent and both represent the function of measuring eosinophil degranulation.

---------- NEW CITATIONS ----------